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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/285,292

04/02/1999

DONNA G. ALBERTSON

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3543

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01/27/2009

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

P O BOX 458

ALAMEDA, CA 94501

EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

01/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/285,292	Applicant(s) ALBERTSON ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-17 and 71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/11/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 11, 2008 has been entered.

2. Claims 1-12, 14-17 and 71 are pending.

Claims 1, 6, 9 and 11 have been amended.

Claim 71 has been added.

Claims 1-12, 14-17 and 71 are examined on the merits.

It is noted by the Examiner Applicants have correctly renumbered claim 71 from previously recited claim 33. Hence, misnumbered claim 33 in the amendment submitted November 11, 2008 has been renumbered 71 consistent with rule 37 CFR 1.126.

Withdrawn Grounds of Objection

Specification

3. The specification is no longer objected to as failing to provide proper antecedent basis for the claimed subject matter because claim 1 has been amended to delete the recitation, "...the endogenous vitamin D 24 hydroxylase (*CYP24*) gene".

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 1-12, 15-17 and 71 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of

Applicants' amendment to claim 1.

6. The rejection of claims 1-12, 14-17 and 71 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting *CYP24* mRNA in human breast tumor *in vitro* specimens treated with 1,25-dihydroxyvitamin D-3 comprising RT-PCR, does not reasonably provide enablement for a method of detecting a predisposition to any cancer comprising detecting the level of *CYP24* nucleic acid or *CYP24* protein in a biological sample and comparing said level with the level from a control sample is withdrawn.

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The rejection of claims 1-12, 14-17 and 71 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendment to claim 1.

New and Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The rejection of claims 1-12, 14-17 and 71 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicants aver they have amended claim 1 to include new text regarding two primers which presumably define both the mRNA and gene corresponding to the target nucleic acid sequences, see page 6 of the Remarks, 2nd paragraph. Applicants assert the *CYP24* gene is a naturally occurring gene and not a gene, which mutation have been introduced, see last sentence on page 6 of the Remarks. These points of view and arguments have been carefully considered, but found unpersuasive.

Amending the claims to include a primer set does not preclude the instant rejection because as Applicants have presented in their Remarks, "[o]ne of skill in the

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art would readily appreciate that these primers [SEQ ID NO: 1 and SEQ ID NO: 2] would amplify *all CYP24 genes that are capable of binding the primers.*", see last full sentence of page 7. The primers would indeed anneal to all *CYP24* genes, including those defined by the specification as "...mutated copy of the gene, or a fragment of the gene", see page 7, lines 10-12. The claims continue to encompass a genus of molecules, such as nucleic acids, proteins and mRNA that are not necessarily wild type forms of *CYP24*. The term reads on a plethora of variant, mutated and alternate forms of *CYP24*. The oligonucleotides defined as SEQ ID NO: 1 and SEQ ID NO: 2 would possibly anneal or bind to recognizable nucleic acid residues of a *CYP24* gene variant with internal mutations, hence providing a false positive and amplifying non-target sequences. Applicants have not described *CYP24* with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the broad genus of molecules set forth in the claimed invention. For the reasons of record and reiterated herein the rejection is maintained.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-12, 14-17 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 9 are vague and indefinite in the recitation because the detection steps are not commensurate with the target molecule. For example, claim 1

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sets forth the detection of CYP24 protein, wherein the protein is amplified by nucleic acid primers, SEQ ID NO: 1 and SEQ ID NO: 2. Similarly, claim 9 reads on level of CYP24 nucleic acid is detected by measuring the level of CYP24 protein. These claimed modes of assaying are not proper. Applicants may obviate the instant rejection by clearly establishing target molecules and the corresponding modes of measuring and detecting in separate claims.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.

21 January 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/285,292	ALBERTSON ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	